



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2002

Mr. James A. Alessi
AirSep Corporation
290 Creekside Drive
Buffalo, NY 14228-2075

Re: K001579
Trade/Device Name: Impulse Select
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NFB

Dear Mr. Alessi:

This letter corrects our substantially equivalent letter of August 31, 2000, regarding the Impulse Select. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NFB as indicated above.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

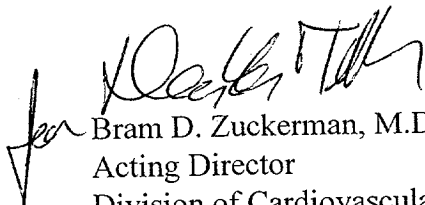
Page 2 – Mr. James A. Alessi

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 INDICATIONS FOR USE

Page 1 of 1

510(k) NUMBER (IF KNOWN): K001579

DEVICE NAME: Impulse Select Oxygen Conserving Device

INDICATIONS FOR USE:

The AirSep Impulse Select Conserving Device is normally to be used in a home or institutional environment by persons who suffer from various forms of Chronic Obstructive Pulmonary Disease (COPD). It is to be used only with a nasal oxygen cannula.

The Impulse Select works in conjunction with a portable oxygen source. Oxygen is delivered in a precise amount at an optimum point in the breathing cycle through a nasal cannula. This form of delivery maximizes the beneficial effects of supplemental oxygen while eliminating unnecessary waste, thus increasing user mobility and ambulatory duration.

The AirSep Impulse Conserving Device is a legally marketed predicate device with the same intended use. The Impulse Select differs from the Impulse in having a second mode of operation that does not adversely affect the safety and effectiveness of the device.

The AirSep Impulse Select has two modes of operation:

- 1) The device can pulse oxygen at flows equivalent to 1, 2, 3, 4, 5, and 6 LPM.
- 2) In addition, a manual valve allows the user to switch to a continuous flow of oxygen at any time.

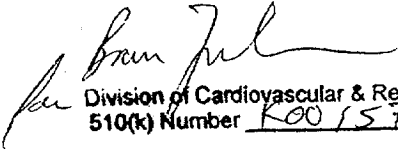
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐
(Optional Format 1-2-96)


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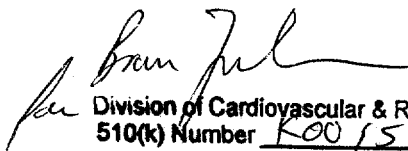
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